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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,988	02/19/2002	Patrick R. Connelly	BTI-1	5092

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EXAMINER

GETZOW, SCOTT M

ART UNIT PAPER NUMBER

3762

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,988

Applicant(s)

CONNELLY ET AL.

Examiner

Scott M. Getzow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-266 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 254-266 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 16-20, 31, 32, 40, 41, 81, 101-105, 116, 117, 125, 126, 186-190, 202, 203, 211 and 212 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Continuation of Disposition of Claims: Claims rejected are 1-15,21-30,33-39,42-80,82-100,106-115,118-124,127-185,191-201,204-210 and 213-253.

Claim Objections

1. Claims 7 and 9 are objected to because of the following informalities:
Claims 7 and 9 are missing. The examiner has not renumbered the claims; the original numbering is used in the rejections below. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claim 113 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Said 'multi-fiber optic bundle' lacks antecedent basis.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1,2,11,21,26,29,33,35,38,42,44,48,50-56,65,68,73,76,84 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsitlik et al (5217010).

As shown in figure 3, for example, Tsitlik teaches a shielded housing 68 as well as control circuitry and leads which contact the patient's heart.

The leads also are shielded and have inductor/capacitor filters to filter out

unwanted interference. See also figure 17 that shows the many layers of shielding for the housing.

5. Claims 87,166 are rejected under 35 U.S.C. 102(b) as being anticipated by Nappholz et al (5766227).

Nappholz teaches a device which when it senses EMI, changes mode of the pacer to one where no sensing is done, i.e. asynchronous. See col. 5, lines 5-10. It is implicit that the leads are covered with a biocompatible material since they are intended to be implanted in the patient's body.

6. Claim 168 is rejected under 35 U.S.C. 102(b) as being anticipated by Brownlee et al (4091818).

Brownlee shows an implantable pacer including a housing and leads, and which can detect EMI by determining the high frequency response resulting from the EMI, as taught in the abstract, for example. It also changes mode to asynchronous upon sensing the high frequency of the EMI.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3,4,12-15,22-25,30,34,39,43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) in view of Luo et al (article titled 'Electromagnetic interference shielding using continuous carbon-fiber carbon-matrix and polymer-matrix composites').

To use carbon and/or polymer for the shielding, as taught by Luo, is considered to be obvious in that such has been shown to be useful in preventing EMI in various electronic devices.

9. Claims 5,6,8,10,27,28,36,37,57-64,66,67,69,70,71,72,74,75,77-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) in view of Lindegren et al (5454837).

Lindegren teaches the use of fiber optics, as well as traditional electrical conductors, to reduce the interference of signals to and from the heart of a patient in an environment where there is electrical noise. To use such fiber optics with the device of Tsitlik would have been obvious and desirable since such would help further reduce EMI from disrupting the operation of the implanted device.

10. Claims 45,46,49,85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) in view of Kim et al (6047210).

Kim teaches the use of digital filtering which can eliminate cross-talk, as well as mode changing ability to change the mode if conditions warrant,

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see abstract for example. To have such features in the pacer of Tsitlik would have been obvious in that such are considered standard in the pacemaker art to achieve the most optimal treatment for the patient.

11. Claims 82,83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) in view of Nappholz et al (5766227).

Nappholz teaches means to differentiate between EMI and a sensor signal, as taught in the abstract, and which also uses a sampling circuit 72. The ability to differentiate between EMI and legitimate signals would have been obvious to have with the device of Tsitlik in order to properly sense signals from the patient with minimal interference from external noise.

12. Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) in view of Hedberg et al (6078835).

Hedberg teaches the ability to detect signals using hydrostatic pressure sensing. To use such with the device of Tsitlik would have been obvious since such has been shown to be effective to determine filling of the heart and thus the proper time period in which to stimulate the patient.

13. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) in view of Busacker et al (6016448).

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Busacker teaches elective replacement indication for a battery in an implantable device. To use such with the device of Tsitlik would have been obvious in that such is important to have in implantable devices in order to insure that the patient has a reliable energy supply for his pacemaker.

14. Claims 88-91,96,97-100,111,114,115,129-131,139,140,141,150,153,158,161 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al (5766227) in view of Luo et al.

To use a shielding around the implanted device of Nappholz would have been obvious since such would protect the device from undesirable interference from various electromagnetic sources. Luo shows the use of shielding using metal, carbon and polymer materials.

15. Claims 92-95,112,113,142-149,151,152,154-157,159,160,162-165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al (5766227) and Luo et al and further in view of Lindegren et al (5454837).

Lindegren show the use of fiber optics in a lead that reduces interference from external sources. To use such fiber optics with the device of Nappholz and Luo would have been obvious in order to further reduce the exposure to EMI caused by external equipment.

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16. Claims 106-110, 118-120, 123, 124, 127, 128, 171, 172 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al (5766227) and Luo et al and further in view of Tsitlik et al (5217010).

To use an electrical filter, such as an inductor/capacitor configuration, as shown by Tsitlik, would have been obvious in that such has been shown in the art to provide reduced electrical interference from noise on the leads.

17. Claim 132 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al (5766227) and Luo et al and further in view of Busacker et al (6016448).

To use the battery ERI shown in Busacker would have been obvious for the reasons mentioned supra.

18. Claims 133-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al (5766227) and Luo et al and further in view of Kim et al (6047210).

To use the digital noise filter (49) of Kim would have been obvious to use with the invention of Nappholz and Luo since such has been shown to be effective in filtering out unwanted signals from signals detected from the sensing electrodes.

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19. Claim 173 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al (5766227) and Luo et al and further in view of Hedberg et al (6078835).

It would have been obvious to use the hydrostatic pressure sensor of Hedberg with the invention of Nappholz and Luo for reasons mentioned supra.

20. Claims 121,122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al (5766227), Luo et al, and Lindegren et al (5454837) and further in view of Tsitlik et al (5217010).

The shielding made of a plurality of layers, as shown in figure 17 of Tsitlik, is deemed to be non-permeable and diffusion resistant. It would have been obvious to use such a shielding with the invention of Nappholz, Luo and Lindegren in order to further protect the device from unwanted EMI.

21. Claims 167,169,170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al (5766227) in view of Nappholz et al (5817136).

The '136 patent shows the ability to sense, among other things, voltage to determine EMI. Since current is proportional to voltage, it would have been obvious to sense for current also. It would have been desirable and obvious to use such sensing means with the '227 patent since such have been shown to be effective in determining EMI.

22. Claims 174,175,178-183, 191-194,197-201,204-210,213-218,220,221,227-229,231,234-243,245,246,252,253 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) in view of Lindegren et al (5454837).

Tsitlik teaches all of the subject matter of the above claims except for the explicit mention of the use of fiber optics for the leads. Lindegren teaches the use of fiber optics for some of the leads. It would have been obvious to use such for the reasons mentioned supra.

23. Claims 176,177,184,185,195,196,232,233 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) and Lindegren et al (5454837) and further in view of Luo et al.

It would have been obvious to use the various types of EMI shielding set forth in Luo for reasons mentioned supra.

24. Claims 219,244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) and Lindegren et al (5454837) and further in view of Hedberg et al (6078835).

It would have been obvious to use the hydrostatic sensing means of Hedberg for reasons mentioned supra.

25. Claims 222,230,247 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) and Lindegren et al (5454837) and further in view of Fitch et al (6575965).

Fitch teaches sensing physiological signals using the displacement of a mirror; see figure 18 where curved mirror 173 moves back and forth. It would have been obvious to use such with the device of Tsitlik and Lindegren since such has been shown to be effective in sensing physiological signals from a patient in a fiber optic environment.

26. Claims 223,248 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) and Lindegren et al (5454837) and further in view of Takaki (6283632).

Takaki teaches detecting physiological signals using the change in a refractive index of a section of cladding (see col. 1, lines 65+). It would have been obvious to use such a method since such has been shown to be effective in measuring physiological signals when fiber optic leads are utilized.

27. Claims 224,249 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) and Lindegren et al (5454837) and further in view of Weiss (5132529).

Weiss teaches the use of an optical strain gauge. It would have been obvious to use such with the invention of Tsitlik and Lindegren since such

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has been shown to be effective in measuring various signals utilizing fiber optics.

28. Claims 225,226,250,251 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al (5217010) and Lindegren et al (5454837) and further in view of Roberts et al (6134459).

Roberts teaches the use of an optical pressure sensor. It would have been obvious to use such with the invention of Tsitlik and Lindegren since such has been shown to be effective for measuring physiological signals using light.

Allowable Subject Matter

29. Claims 16-20,31,32,40,41,81,101-105,116,117,125,126,186-190,202,203,211,212 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

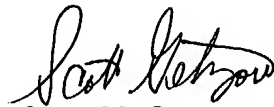
30. Claims 254-266 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (703) 308-2997. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Scott M. Getzow
Primary Examiner
Art Unit 3762

smg